K131015

510(k) Summary

September 30, 2013

OCT 08 2013

Cook Biotech Incorporated

Biodesign® Onlay Dural Graft

Manufacturer Name: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906
Telephone: +1 (765) 497-3355
FAX: +1 (765) 807-7709

Official Contact: Perry W. Guinn

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Biodesign Onlay Dural Graft
Common Name:	Dura Substitute
Classification Regulations:	Class II, 21 CFR §882.5910 (84GXQ)

INDICATIONS FOR USE:

The Biodesign Onlay Dural Graft is intended for use as a dura substitute for the repair of dura mater. The device is provided sterile and intended for one-time use.

DEVICE DESCRIPTION:

The Biodesign Onlay Dural Graft is composed of a bioabsorbable, extracellular collagen matrix (Small Intestinal Submucosa, SIS). The SIS material that comprises the Biodesign Onlay Dural Graft is identical in composition and technology to that of its predicate Durasis Dural Substitute (K031850), also manufactured by Cook Biotech Incorporated and similar to its other predicate, DuraGen II *Dural Regeneration Matrix* (K043427) manufactured by Integra LifeSciences. The Biodesign Onlay Dural Graft is implanted as a dura substitute providing a scaffold which becomes infiltrated by the patient's cells and is remodeled into native tissue. The device is packaged in a lyophilized (dried) state and supplied sterile in a sealed double pouch system. The Biodesign Onlay Dural Graft can be placed without sutures during skull base dural repair.

EQUIVALENCE TO MARKETED DEVICES

The Biodesign Onlay Dural Graft is similar with respect to intended use, and identical with respect to materials and technological characteristics to the predicate devices in terms of section 510(k) substantial equivalence, as shown through bench (ultimate

tensile strength, thickness, burst strength), animal (where the device was implanted as an onlay in a rat study), and biocompatibility testing (genotoxicity, direct contact *in vitro* hemolysis, cytotoxicity, muscle implantation, acute intracutaneous reactivity, sensitization, acute systemic toxicity, pyrogenicity, LAL endotoxins, subchronic systemic toxicity), and clinical studies using the device in cranial base dural repair.

Bench testing

The following mechanical tests were performed on finished, terminally sterilized devices:

- Suture retention strength
- Ultimate tensile strength
- Burst strength test

The tests provided evidence that the Biodesign Onlay Dural Graft performed similarly to its predicate devices.

Biocompatibility testing

The following biocompatibility tests were performed on sterilized SurgiSIS Mesh, which is identical in composition to the Biodesign Onlay Dural Graft (according to the ISO 10993-1 standard):

- Genotoxicity
- Direct contact *in vitro* hemolysis
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- ISO Sensitization
- Acute systemic toxicity
- Pyrogenicity
- LAL endotoxins
- Subchronic systemic toxicity

The results of these tests provided evidence that the Biodesign Onlay Dural Graft meets biocompatibility requirements of the ISO standard.

Animal Study

An animal study using finished devices in a rat model where the device was implanted using an onlay technique showed that the device performed adequately with no physiological, histological or functional evidence of adverse health effects were observed.

Table of Substantial Equivalence

Device	Biodesign® Onlay Dural Graft	DuraGen II *Dural Regeneration Matrix*	Durasis Dural Substitute
Manufacturer	Cook Biotech Incorporated	Integra LifeSciences	Cook Biotech Incorporated
510(k) Number	K131015	K043427	K031850
Indications for Use	Intended for use as a dura substitutefor repair of dura mater.	DuraGen II *Dural Regeneration Matrix* is indicated as a dura substitute for the repair of dura mater.†	Intended for use as a dura substitute for repairing dura mater.
Material	Porcine small intestinal submucosa Primarily Types I, III, IV and VI collagen	Bovine tendon collagen	Porcine small intestinal submucosa Primarily Types I, III, IV and VI collagen.
Dimensions	1 x 2 cm, 1 x 3 cm, 2 x 3 cm, 2.5 x 2.5 cm, 2.5 x 7.5 cm, 4 x 7 cm, 5 x 5 cm, 7.5 x 7.5 cm, 7 x 10 cm	1 x 1 in to 5 x 7 in (2.5 x 2.5 cm to 12.7 x 17.8 cm)	2 x 2 cm to 10 x 20 cm
Thickness	154 µm to 680 µm	3.0 mm§	100 µm to 800 µm

† Cleared for use as an onlay.

§ Zerris VA, James KS, et al. Repair of dura mater with processed collagen devices. J. Biomedical Materials research Part B: Applied Biomaterials. 2007; 83:580-588.

CONCLUSION:

The Biodesign® Onlay Dural Graft is substantially equivalent to its predicate devices in terms of physical characteristics and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 8, 2013

Cook Biotech Incorporated
% Mr. Perry W. Guinn
Vice President, Quality Assurance & Regulatory Affairs
1425 Innovation Place
West Lafayette, IN 47906-1000

Re: K131015
Trade/Device Name: Biodesign® Onlay Dural Graft
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: September 5, 2013
Received: September 6, 2013

Dear Mr. Guinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131015

Device Name: Biodesign® Onlay Dural Graft

Indications For Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S